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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/765,034 | 01/17/2001 | Joseph A. Hedrick | CN01084 | 6960 |

24265 7590 10/02/2002

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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| EXAMINER |
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LAZAR WESLEY, ELIANE M

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| ART UNIT | PAPER NUMBER |
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1646

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,034

Applicant(s)

Hedrick

Examiner

Eliane Lazar-Wesley

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-20 is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, drawn to a polypeptide, classified in class 530, subclass 350.
 - II. Claims 4-13, drawn to a polynucleotide, an expression system, a process for producing a host cell, a process for producing a polypeptide, classified in class 435, subclass 69.1.
 - III. Claim 3, drawn to an antibody, classified in class 530, subclass 387.1
 - IV. Claims 14-15, as drawn to a method of identifying an agonist or antagonist of the polypeptide, by measuring the amount of labeled adenosine bound, classified in class 436, subclass 504.
 - V. Claim 16, as drawn to a method of identifying an antagonist of the polypeptide, by measuring a cellular function, classification depending on the function measured.
 - VI. Claims 17-18, as drawn to an agonist, classification depending on the compound.
 - VII. Claims 17-18, as drawn to an antagonist, classification depending on the compound.
 - VIII. Claim 19, drawn to a method of treatment using an agonist, classification depending on the nature and structure of the agonist.
 - IX. Claim 19, drawn to a method of treatment using an antagonist, classification depending on the nature and structure of the antagonist.

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X. Claim 20, drawn to measuring expression of an adenosine receptor using a PCR method, classified in class 435, subclass 91.2.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III and VI-VII are directed to products that are distinct both physically and functionally, and are therefore patentably distinct. The nucleic acids molecules encoding a polypeptide of invention II are related to the protein of invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as synthetic peptides synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of invention I are related to the antibodies of invention III by virtue of being cognate antigens, which may be used for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the proteins can be used in other and materially different processes from the use for production of the antibody, such as in pharmaceutical compositions, or in a diagnostic assay or for therapeutic purposes.

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The agonist and antagonist of Groups VI and VII are mutually exclusive, and are patentably distinct from the products of Groups I-III.

The methods of Groups IV, V, VIII, IX and X are independent and patentably distinct, as they use different reagents, have different steps and reach different goals.

Inventions VI and VIII, and Inventions VII and IX, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of treatment can be practiced with different products, like a promotor of gene expression or an anti-sense RNA for example.

Inventions II and X are related as product and process of use. In the instant case, the polynucleotide as claimed can be used in a materially different process, like the recombinant expression of a polypeptide.

Inventions I and IV-X, Inventions II and IV-IX, Inventions III and VI, VIII, X, respectively, are unrelated, as they are not disclosed as capable of use together.

Invention III and each of Inventions IV, V, VII, IX are related as product and process of use. In the instant case, the antibody can be used for affinity purification, and the methods can use antagonists other than an antibody.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because the searches required for each of the groups are different, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.


Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

October 01, 2002

ELW


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600